K111408

OCT 17 2011

510(k) Summary

GENERAL INFORMATION

5.1 Type of Submission

Special 510(k) Submission

Submission date: 10/05/2011

5.2 Submitter

Name: CareFusion Germany 234 GmbH

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Contact person in Germany:

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Filter, Bacterial, Breathing-Circuit
(CFR 868.5260, Product Code CAH)

5.5 Trade Name
MicroGard II

5.6 Device Classification
This is a Class II device

5.7 Classification Panel
73 Anesthesiology Part 868
Code CAH

5.8 Reason for Premarket Notification
--- Modification of legally marketed devices ---
Change to the existing CareFusion MicroGard filter

5.9 Legally predicate marketed device
SensorMedics MicroGard Microbial Filter
K934272 Code CAH

5.10 Predicate Device Company
CareFusion

5.11 Device Description
The CareFusion MicroGard II filter is a disposable barrier type filter intended to protect both, patient and instrument, by preventing the transmission of pathogens by droplets and aerosolized particles between the patient and the spirometer, or pulmonary function testing instrument.

5.12 Intended Use Statement
The CareFusion MicroGard® II filter series is indicated for use in prevention of contamination of pulmonary function testing equipment and associated valves and hoses by aerosols and particulates which may be present in a patient's exhaled gas volumes. The MicroGard® II filter should be used only on patients with a minimum body weight of 27.5 kg.

5.13 Required Components
- Filter MicroGard IIB (filter with integrated mouthpiece)
- Filter MicroGard IIC (filter with cone OD 30 for adapting a mouthpiece)
- Instruction for Use

5.14 Summary Table of Comparison

Comparison with the predicate device

	Sensormedics MicroGard K934272	**MicroGard® II** (MicroGard IIB / MicroGard IIC)
Indications for Use	The SensorMedics MicroGard™ Microbial filter is indicated for use in prevention of contamination of pulmonary function testing equipment and associated valves and hoses by aerosols and particulates which may be present in a patient's exhaled gas volumes.	The CareFusion MicroGard® II filter series is indicated for use in prevention of contamination of pulmonary function testing equipment and associated valves and hoses by aerosols and particulates which may be present in a patient´s exhaled gas volumes. The MicroGard® II filter should be used only on patients with a minimum body weight of 27.5 kg.
Patient population	no limitation	According ATS recommendation
Housing material	Polystyrene resin	Polystyrene 454C
Filter material	3M GS-100	Polypropylene & Modacrylic fiber
Dimensional specifications	length 3,94 inch (10,01 cm) diameter 3,54 inch (8,99 cm)	MicroGard IIB: length = 10,6 cm diameter = 9,0 cm
		MicroGard IIC: length = 10,7 cm diameter = 9,0 cm
Connection to patient user interface	30mm ID & 30mm OD Tapered Port	MicroGard IIB: 30mm ID & integrated mouthpiece with tooth marker
		MicroGard IIC: Identical

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Performance specification	Resistance: 0.7 cmH2O/L/sec @ 12L/sec	Resistance: < 0.4 cmH2O/L/sec @ 1L/sec
	Dead Space: 50ml	Dead Space: 55ml
	Filter efficiency: BFE > 99% (at 30l/min) VFE > 99% (at 30l/min)	Filter efficiency: BFE > 99% (at 30l/min) VFE > 99% (at 30l/min)
	----------	Filter efficiency B. atrophaeaus > 96% (at 750l/min) MS-2 coliphage > 97% (at 750l/min)
Patient contacting parts	no direct contact to patient	MicroGard IIB: integrated mouthpiece with direct contact to the patient
		MicroGard IIC: Identical
Sterilization	single patient use	Identical

Discussion to the device differences:

The insignificant differences are:

The MicroGard II filter is available in two types, the MicroGard IIB with integrated mouthpiece and the MicroGard IIC without mouthpiece.

The indication for use for the MicroGard II is similar to the Sensormedics MicroGard filter. Only a patient body weight recommendation was added according to the ATS recommendation on dead space for younger patients.

The change in filter material was necessary as the MicroGard II Bacterial/Viral Filter is constructed as a high flow filter with a filter efficiency of more than 96% tested at a high flow of 750 l/min.

The MicroGard IIB is equipped with an integrated mouthpiece and has direct patient contact. For the material a biocompatibility test was accomplished at Namsa test laboratory.

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the MicroGard II Bacterial/Viral Filter:

- The modification for the above device was developed in accordance with the CareFusion Design and Development SWI (0301-5001-000-SWI).
- The modifications were developed according to IEC 62366 (Usability) standard.
- The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA) according standard ISO 14971.
- Biocompatibility for the patient contacting material has been tested according ISO 10993-1 standard at Namsa test laboratory in the USA.
- Filtration efficiency has been tested at Nelson test laboratory in the USA and at Health Protection Agency in the UK.

5.16 Conclusion

Based on the above, CareFusion Germany 234 GmbH concludes that the MicroGard II is substantially equivalent to the legally marketed predicate device, the "Sensormedics MicroGard K934272" and is safe and effective for its intended use, and performs at least as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Germany 97204

OCT 17 2011

Re: K111408
Trade/Device Name: MicroGard® II
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: October 5, 2011
Received: October 11, 2011

Dear Mr. Niedermeyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111408

Device Name: MicroGard® II

Indications for Use:

The CareFusion MicroGard® II filter series is indicated for use in prevention of contamination of pulmonary function testing equipment and associated valves and hoses by aerosols and particulates which may be present in a patient's exhaled gas volumes. The MicroGard® II filter should be used only on patients with a minimum body weight of 27.5 kg.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schuttinger

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 111408